

EXHIBIT 1

Excerpts from the Deposition of
Jay W. Heinecke, M.D.
Dated July 17, 2019

UNITED STATES DISTRICT COURT
DISTRICT OF NEVADA

AMARIN PHARMA, INC., et al.,

Plaintiffs,

vs.

HIKMA PHARMACEUTICALS USA INC.,
et al.,

Defendants.

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VIDEOTAPED DEPOSITION OF

JAY W. HEINECKE, M.D.

San Francisco, California

Wednesday, July 17, 2019

Reported by Stenographer

MARY J. GOFF

CSR No. 13427

Job No. 162979

Videotaped Deposition of
JAY W. HEINECKE, M.D., Volume I, taken on behalf of
Plaintiffs, at Winston & Strawn LLP, 101 California
Street, San Francisco, California 94111, beginning
at 8:04 a.m. and ending at 4:12 p.m., on July 17,
2019, before MARY J. GOFF, California
Certified Shorthand Reporter No. 13427.

APPEARANCES:

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Videographer:
Marcus Majers

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Volume I

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BY MR. REIG-PLESSIS --

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1	San Francisco, California	10:20	1	With me is my colleague, Eric	08:04
2	July 17, 2019	10:20	2	Sonnenschein; and Joe Kennedy of Amarin Pharmaceuticals.	08:04
3	8:04 a.m.	10:20	3	MR. REIG-PLESSIS: I'm Eimeric Reig of Winston & Strawn, on behalf of the Hikma Defendants and the witness.	08:04
4	10:20		4	THE VIDEOGRAPHER: And has anyone joined on the phone yet?	08:04
5	THE VIDEOGRAPHER: Good morning. This is the start of media labeled No. 1 of the video recorded deposition of Dr. Jay W. Heinecke, in the matter of Amarin Pharma, Inc., et al, versus Hikma Pharmaceuticals USA Inc., et al., in the United States District Court, District of Nevada, Case No.: 2:16-cv-02525-MMD-NJK; Consolidated with: 2:16-cv-02562-MMD-NJK.	08:02	5	MR. REIG-PLESSIS: I don't think so.	08:04
6			6	MR. SIPES: Okay. Great.	08:04
7	This deposition is being held at Winston & Strawn, 101 California Street, San Francisco, California, on July 17, 2019, at approximately 8:04 a.m.	08:03	7	JAY W. HEINECKE, M.D., being first duly sworn or affirmed to testify to the truth, the whole truth, and nothing but the truth, was examined and testified as follows:	08:04
8			8	EXAMINATION	08:04
9	My name is Marcus Majers. I'm the legal video specialist from TSG Reporting, Inc., headquartered at 747 Third Avenue, New York, New York. The court reporter is Mary Goff, in association with TSG Reporting.	08:03	9	BY MR. SIPES:	08:04
10			10	Q Good morning. Thank you for coming in this morning.	08:04
11	Will all counsel present please introduce themselves.	08:04	11	Could you please state your name and spell it for the record?	08:04
12	MR. SIPES: Christopher Sipes of Covington & Burling LLP, on behalf of the Plaintiff.	08:04	12	A Yes. My name is Jay Walter Heinecke, HEINECKE; J A Y; Walter, W A L T E R.	08:04
13			13	Q And where do you reside?	08:04
14			14	A I reside in Seattle, Washington.	08:04
15			15	Q And you are currently employed?	08:04
16			16		
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18			18		
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20			20		
21			21		
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23			23		
24			24		
25			25		

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<p>1 A I'm currently provide by the University of 08:04 2 Washington. 08:04 3 Q And what is your work address? 08:04 4 A My work address would be the University of 08:05 5 Washington, 850 Republican Street, Seattle 98109. 08:05 6 Q Okay. Have you been deposed before? 08:05 7 A I have never been deposed as an expert 08:05 8 witness. 08:05 9 Q You have been deposed as a fact witness? 08:05 10 A As a what? 08:05 11 Q Have you been deposed as a fact witness? 08:05 12 Have you ever been deposed in any capacity? 08:05 13 A I have. 08:05 14 Q Okay. How many times? 08:05 15 A One time. 08:05 16 Q Okay. I will go through the rules. I 08:05 17 suspect you -- you know them, having been through 08:05 18 it. 08:05 19 But first, you understand that you are 08:05 20 under oath today and are required to answer my 08:05 21 questions truthfully? 08:05 22 A Yes. 08:05 23 Q If you don't understand a question, please 08:05 24 let me know and I will attempt to clarify it. 08:05 25 Otherwise, I will assume that you understood it; is 08:05</p>	<p>1 that fair? 08:05 2 A Yes. 08:05 3 Q This is not an endurance test. If at some 08:05 4 time you need a break, let me know and we'll try to 08:05 5 endeavor to find a good breaking point for you. 08:05 6 A Okay. 08:05 7 Q You understand that the court reporter is 08:05 8 taking down a transcript, so you'll need to answer 08:05 9 audibly with verbal responses? 08:05 10 A I do. 08:06 11 Q Also, you -- your counsel may from time to 08:06 12 time object, but you'll need to answer the 08:06 13 questions, if you understand them, unless you're 08:06 14 instructed not to answer by counsel. 08:06 15 Do you understand? 08:06 16 A I understand. 08:06 17 Q Is there any reason why you cannot give 08:06 18 complete and truthful testimony today? 08:06 19 A No, not that I'm aware after. 08:06 20 Q Okay. And as far as you're -- you don't 08:06 21 have any medical condition or medications that might 08:06 22 interfere with your ability to answer truthfully? 08:06 23 A No. 08:06 24 Q Let me hand to you three documents that 08:06 25 have been marked as Exhibits 1, 2, and 3 in the 08:06</p>
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<p>1 case. 08:06 2 (Exhibit 1 was marked for identification 08:06 3 and is attached to the transcript.) 08:06 4 (Exhibit 2 was marked for identification 08:06 5 and is attached to the transcript.) 08:06 6 (Exhibit 3 was marked for identification 08:06 7 and is attached to the transcript.) 08:06 8 A Okay. 08:06 9 Q (BY MR. SIPES) Do you recognize 08:06 10 Exhibits 1, 2, and 3 as the reports that you 08:06 11 prepared in this case? Since you have Exhibit 1 in 08:06 12 your hands, if you would turn to page 241 of 08:07 13 Exhibit 1, if you're looking for your signature. 08:07 14 A Thank you. 08:07 15 Q That -- that is your signature -- 08:07 16 A Yes -- 08:07 17 Q -- on page 241 of Exhibit 1? 08:07 18 A -- that's my signature on -- 08:07 19 Q And you -- why don't we deal with 08:07 20 Exhibit 1. 08:07 21 A You -- 08:07 22 Q You have got it in front of you. 08:07 23 A Yeah. Yeah. 08:07 24 Do I need to look at the signatures on the 08:07 25 other ones as well? 08:07</p>	<p>1 Q We can go through them one at a time, I -- 08:07 2 A Okay. 08:07 3 Q -- think is easiest. 08:07 4 A Fine. 08:07 5 Q And Exhibit 1 is the -- your opening 08:07 6 report -- 08:07 7 A Yes. 08:07 8 Q -- in this case, correct? 08:07 9 And you have signed it on or about 08:07 10 March 11 of 2019? 08:07 11 A Yes. 08:07 12 Q And you understand that you -- you signed 08:07 13 your expert report under penalty of perjury? 08:07 14 A Yes. 08:07 15 Q And did you endeavor to make what you 08:07 16 stated in your opening report -- and first of all, 08:08 17 is it all right if we refer to your -- Exhibit 1 as 08:08 18 your opening report? 08:08 19 A That's fine. 08:08 20 Q And did you endeavor to -- to make your 08:08 21 statements in Exhibit 1 to be as truthful and 08:08 22 accurate as possible? 08:08 23 A I endeavored to make the statements as 08:08 24 truthful and accurate as possible. 08:08 25 Q Are you aware of any errors or corrections 08:08</p>

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<p>1 Q (BY MR. SIPES) In -- in your opening 09:35 2 report where you opined on the obviousness of the 09:35 3 invention, did you rely on EPANOVA in forming your 09:35 4 opinions? 09:35 5 A Since I can't remember the specific date, 09:35 6 I would have to do further research on that question 09:35 7 to answer that. 09:35 8 Q Okay. And similarly, sitting here today, 09:35 9 is it your opinion that Omtryg is prior art? 09:35 10 A Again, I don't remember the specific date 09:35 11 for that, and so I would have to research that 09:35 12 further in order to answer the question. 09:35 13 Q All right. And do you understand that 09:35 14 Omtryg is neither Lovaza, nor Epadel? 09:35 15 A Yes. 09:35 16 Q And you -- sitting here today, you're not 09:35 17 prepared to answer one way or the other as to 09:35 18 whether or not, in your opinions of obviousness 09:35 19 expressed in your opening report, you rely upon 09:35 20 Omtryg? 09:35 21 MR. REIG-PLESSIS: Objection to form. 09:35 22 A Could you be more specific about exactly 09:35 23 what you are referring to? 09:35 24 Q (BY MR. SIPES) You -- you recall in your 09:35 25 opening report, putting together opinions on 09:35</p>	<p>1 obviousness? 09:36 2 A Yes. 09:36 3 Q Okay. Do you -- okay. 09:36 4 Do you recall sitting here today whether 09:36 5 or not, in forming your opinion of obviousness that 09:36 6 you expressed in your opening report, you relied on 09:36 7 Omtryg as part of the prior art? 09:36 8 A You would have to refer me to the specific 09:36 9 point where I do that. 09:36 10 Q Okay. I -- I don't find it in your 09:36 11 opening report. But I'm not the master of your 09:36 12 opinions, which -- 09:36 13 A Yeah. 09:36 14 Q -- is why I asked. 09:36 15 A Okay. 09:36 16 Q So I take it sitting here today, you do 09:36 17 not recall relying on Omtryg in forming your 09:36 18 opinions of obviousness that you expressed in your 09:36 19 opening report? 09:36 20 A I do not recall that. 09:36 21 Q Okay. So let's turn to your opening 09:36 22 report, paragraph 18. 09:36 23 A Paragraph 18. 09:36 24 Q 18, yeah. You state, I have been asked by 09:36 25 counsel to offer my opinions regarding the 09:37</p>
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<p>1 obviousness of the asserted claims from the point of 09:37 2 view of a person of ordinary skill in the art. 09:37 3 Do you see that? 09:37 4 A Yes. 09:37 5 Q And the counsel you referred to there 09:37 6 is -- is defendants' counsel, I take it, correct? 09:37 7 A Yes. 09:37 8 Q And as you note in paragraph 25, you are 09:37 9 not a lawyer, correct? 09:37 10 A Correct. 09:37 11 Q So you relied upon defendants' counsel's 09:37 12 instructions regarding the legal standards for 09:37 13 obviousness, correct? 09:37 14 A Yes, in consultation with the lawyers. 09:37 15 Q Right. And the -- the legal standards 09:37 16 that you applied in formulating your opinions on 09:37 17 obviousness are set forth in paragraphs 26 to 31 of 09:37 18 your opening report, correct? 09:37 19 A Yes. 09:37 20 Q And the legal standard you used is the 09:37 21 legal standard that you set forth from counsel; you 09:37 22 didn't rely on your own independent understanding of 09:37 23 obviousness, correct? 09:38 24 A I -- I consulted with counsel, taking 09:38 25 advantage of their expertise, to provide my 09:38</p>	<p>1 understanding of what these concepts meant. 09:38 2 Q You -- in your opening report, you do not 09:38 3 express any opinions concerning the legal defense of 09:38 4 "anticipation," correct? 09:38 5 A I don't know what that means. Could you 09:38 6 redefine that question, please? 09:38 7 Q I -- you are -- do you have an 09:38 8 understanding of the legal defense of 09:38 9 "anticipation"? 09:38 10 A Of anticipation? I'm not recalling 09:38 11 anything about anticipation. 09:38 12 Q Okay. So -- 09:38 13 A I would have to do further research on -- 09:38 14 Q Okay. 09:38 15 A -- that point. 09:38 16 Q So to the best of your recollection, you 09:38 17 are not offering an opinion that the asserted claims 09:38 18 are invalid for anticipation, correct? 09:38 19 A Could you define what you mean by "for 09:38 20 anticipation"? 09:38 21 Q Well, I would like to ask the question 09:38 22 here. And if you don't understand anticipation, 09:39 23 that's fine. 09:39 24 Do you find that you can't answer the 09:39 25 question, whether or not you're offering an opinion 09:39</p>

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<p>1 as to whether the claims are invalid for 09:39 2 anticipation? 09:39 3 A Could you define what "anticipation" means 09:39 4 for me? 09:39 5 Q Anticipation in the patent law refers to 09:39 6 invalid under Section 102 of the patent code. 09:39 7 Are you -- do you -- do you believe that 09:39 8 you have offered an opinion that the claims are 09:39 9 invalid for anticipation? 09:39 10 MR. REIG-PLESSIS: I object to foundation 09:39 11 to this line of questions. 09:39 12 A I -- I would have to have more information 09:39 13 about exactly what that particular piece of 09:39 14 information was. 09:39 15 Q (BY MR. SIPES) All right. So to the best 09:39 16 of your recollection, you did not rely on legal 09:39 17 standards for anticipation in forming your opinions 09:39 18 in this case? 09:39 19 A I -- I can't answer that question, because 09:39 20 I don't know what the definition of legal -- of 09:39 21 "anticipation" is. 09:39 22 Q Do you offer an opinion that the asserted 09:40 23 claims -- are -- are you familiar with the legal 09:40 24 concept of "lacking novelty"? 09:40 25 A Yes. 09:40</p>	<p>1 Q Okay. Was your understanding of lacking 09:40 2 novelty? 09:40 3 MR. REIG-PLESSIS: Objection to form. 09:40 4 A I would go with what is stated in the 09:40 5 opening report. Could you refer specifically to 09:40 6 that? 09:40 7 Q (BY MR. SIPES) Where in your opening 09:40 8 report do you discuss novelty? 09:40 9 A I would have to research through here to 09:40 10 find those -- 09:40 11 Q Okay. 09:40 12 A -- examples. 09:40 13 Q Okay. Do you understand how novelty 09:40 14 differs from nonobvious -- from obviousness? 09:40 15 MR. REIG-PLESSIS: Objection to form and 09:40 16 foundation. 09:40 17 MR. SIPES: Counsel, we're -- we're just 09:40 18 wondering what the scope of his opinions are. 09:40 19 MR. REIG-PLESSIS: I can represent that 09:40 20 it's not about anticipation. 09:40 21 MR. SIPES: All right. Thank you. 09:40 22 Q (BY MR. SIPES) Now, if you'll turn to 09:40 23 paragraph 409 -- 09:40 24 A 409. In the opening report? 09:40 25 Q -- in the opening report -- 09:41</p>
Page 96	Page 97
<p>1 A Okay. Thank you. 09:41 2 Q -- you refer to -- in paragraph 409, 09:41 3 to "Claim 18B, indefinite because of uncertainty 09:41 4 about the reference to second subject. 09:41 5 Do you see that? 09:41 6 A I'm sorry. Which -- which paragraph is 09:41 7 that again? 09:41 8 Q 409. 09:41 9 Do you see, It is my understanding from 09:41 10 counsel, that defendants also contend that second 09:41 11 subject is not being defined in Claim 17 -- not 09:41 12 being defined in Claim 17, renders Claim 18 09:41 13 indefinite to the person of ordinary skill in the 09:41 14 art as not understanding who the second subject is 09:41 15 in Claim 18? 09:41 16 A As I state here, and as you said, in 09:41 17 concert with counsel, this is what I understand. 09:41 18 Q Okay. Aside from this issue with 09:41 19 Claim 18, you do not express an opinion that any 09:42 20 other claim is invalid as indefinite. Do you recall 09:42 21 forming any opinions about the definiteness of the 09:42 22 claims? 09:42 23 A I would have to research this further. I 09:42 24 don't recall those specific -- 09:42 25 Q Okay. 09:42</p>	<p>1 A -- details. 09:42 2 Q And are you familiar with -- sitting here 09:42 3 today, do you recall being instructed on the defense 09:42 4 of lack of written description? 09:42 5 A I would have to go back and look at the 09:42 6 document. 09:42 7 Q But to the best of your recollection 09:42 8 sitting here today, you did not offer opinions in 09:42 9 your opening report concerning the defense of lack 09:42 10 of written description, correct? 09:43 11 A To the best of my knowledge right now, but 09:43 12 I would have to research that further in order to 09:43 13 answer the question. 09:43 14 Q Now, if you'll turn to your discussion of 09:43 15 the claim construction order in the case. That's in 09:43 16 paragraph 32 of your opening report. 09:43 17 A Okay. 09:43 18 Q You state, It is my understanding that the 09:43 19 court entered a claim construction order in this 09:43 20 case on August 10, 2018, which define the following 09:43 21 claim terms to have the meanings set forth below. 09:43 22 Do you see that? 09:43 23 A Yes. 09:43 24 Q And the understanding you refer to is an 09:43 25 understanding that came from discussions with 09:43</p>

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1	defendants' counsel? 09:43	1	combinations of these terms are used at different 09:44
2	A Yes. 09:43	2	times throughout the document. 09:44
3	Q And so the -- the definitions that were 09:43	3	Q But in forming your opinions, you 09:44
4	set forth in the Court's claim construction order, 09:43	4	endeavored to apply the Court's claim construction, 09:44
5	those were provided to you by counsel? 09:43	5	correct? 09:44
6	A Yes, they were. 09:43	6	A I did. Correct. 09:44
7	Q And did you apply, in forming your 09:43	7	Q And do you believe that you applied the 09:45
8	opinions, the constructions that are set forth in 09:44	8	claims -- the Court's claim construction in forming 09:45
9	paragraph 32 of your report? 09:44	9	your opinions? 09:45
10	A I did, to the best of my ability. 09:44	10	A To the best of my ability. 09:45
11	Q Okay. And with regard to Subsection C of 09:44	11	Q Okay. Now, in -- in Subsection C, you 09:45
12	paragraph 32, you refer to "claim limitations 09:44	12	state that the "claim terms concern -- concerning 09:45
13	involving LDL-C." 09:44	13	LDL-C are not indefinite." 09:45
14	Do you see that? 09:44	14	Do you see that? 09:45
15	A Yes, I do. 09:44	15	A I do. 09:45
16	Q And one of the constructions for some of 09:44	16	Q That an understanding that came to you 09:45
17	the terms is "without a clinically meaningful 09:44	17	from defendants' counsel? 09:45
18	increase in LDL-C"? 09:44	18	A It is. 09:45
19	A Yes. 09:44	19	Q And you don't dis -- you don't dispute 09:45
20	Q And did you -- is that the meaning that 09:44	20	that in your report, correct? 09:45
21	you applied in forming your opinions in the case? 09:44	21	A Well, I might need more specific examples 09:45
22	A I think it depends on the particular 09:44	22	for what you are referring to. But in general, I 09:45
23	circumstances of the claims. There are many, many 09:44	23	try to adhere to this definition, as advised by my 09:45
24	claims in this particular set of documents and many 09:44	24	counsel. 09:45
25	different arguments, and so I believe different 09:44	25	Q All right. Thank you. Did you review -- 09:45
Page 100		Page 101	
1	scratch that. 09:45	1	A 57. 09:46
2	Let me ask you to turn to your reply 09:45	2	MR. REIG-PLESSIS: That's on page 20. 09:46
3	report. 09:45	3	A Yes. Okay. Repeat the question, please. 09:46
4	A Is this 2 or 3? 09:45	4	Q (BY MR. SIPES) In paragraph 57, you cite 09:46
5	MR. REIG-PLESSIS: It's 3. 09:45	5	to a paper by Bill Harris -- 09:46
6	Q (BY MR. SIPES) It's 3. So for clarity, I 09:46	6	A Yes. 09:46
7	have tried to use -- 09:46	7	Q -- from 2006. 09:46
8	A I know. 09:46	8	Do you see that? 09:46
9	Q -- the terms that you used -- 09:46	9	A Yes. 09:46
10	A I know. 09:46	10	Q Okay. Do you know Bill Harris? 09:46
11	Q -- so that -- Exhibit 2 is your rebuttal 09:46	11	A I do not. 09:46
12	report, and Exhibit 3 is your reply -- 09:46	12	Q Okay. And you quote that the 2006 Harris 09:46
13	A Yeah. 09:46	13	paper is stating, The mechanism by which n-3 [i.e. 09:46
14	Q -- report? Is that consistent with your 09:46	14	omega-3] fatty acids reduced triglyceride levels in 09:47
15	understanding? 09:46	15	humans remains speculative and "an unanswered 09:47
16	A Yes. 09:46	16	question." 09:47
17	Q Okay. All right. Paragraph 57. 09:46	17	Do you see that? 09:47
18	A Yes. 09:46	18	A Yes. 09:47
19	Q In paragraph 57, you cite a paper by Bill 09:46	19	Q And when you refer to "n-3" -- that is, 09:47
20	Harris that was published in 2006. 09:46	20	omega-3 fatty acids -- you include in there DHA and 09:47
21	Do you see -- 09:46	21	EPA, correct? 09:47
22	A Yeah, you -- 09:46	22	A Yes. 09:47
23	Q -- that? 09:46	23	Q And you would include both their ethyl 09:47
24	A -- gave me the wrong thing here. 09:46	24	esters and the free fatty acids, correct? 09:47
25	MR. REIG-PLESSIS: Exhibit 3. 09:46	25	A Yes. 09:47

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<p>1 Q The -- do you have a list of -- of 10:41</p> <p>2 products to -- to -- that are FDA approved to treat 10:41</p> <p>3 very high triglycerides? 10:41</p> <p>4 A Yes. 10:41</p> <p>5 Q And that's fibrates, niacin, Lovaza, 10:41</p> <p>6 EPANOVA, and Omtryg. 10:41</p> <p>7 Do you see that? 10:41</p> <p>8 A Yes, I do. 10:41</p> <p>9 Q And of course, VASCEPA is also approved to 10:41</p> <p>10 treat very high triglycerides? 10:41</p> <p>11 A Yes. 10:41</p> <p>12 Q Statins are not approved to treat very 10:41</p> <p>13 high triglycerides, correct? 10:41</p> <p>14 A Correct. 10:41</p> <p>15 Q And the reason for that is the TG-lowering 10:41</p> <p>16 effect of statins is -- is very modest, correct? 10:41</p> <p>17 A I -- I don't think that's quite correct. 10:41</p> <p>18 Q Okay. 10:41</p> <p>19 A Actually, statins will lower triglycerides 10:41</p> <p>20 by up to 50 percent in people with high 10:41</p> <p>21 triglycerides or very high triglyceride levels. 10:41</p> <p>22 Q Do you understand why statins are not 10:41</p> <p>23 approved to treat very high triglycerides? 10:41</p> <p>24 MR. REIG-PLESSIS: Objection to form. 10:41</p> <p>25 A I am not aware of the reason why. 10:42</p>	<p>1 Q (BY MR. SIPES) All right. In terms of the 10:42</p> <p>2 list of products that are approved to treat very 10:42</p> <p>3 high triglycerides, the only product that has been 10:42</p> <p>4 shown to reduce triglycerides in very high 10:42</p> <p>5 triglyceride patients without raising LDL-C is 10:42</p> <p>6 VASCEPA, correct? 10:42</p> <p>7 MR. REIG-PLESSIS: Objection to form. 10:42</p> <p>8 A Can you restate the question so you're -- 10:42</p> <p>9 Q (BY MR. SIPES) There -- you have -- the 10:42</p> <p>10 list of products which have been approved to reduce 10:42</p> <p>11 triglycerides in very high triglyceride patients is 10:42</p> <p>12 fibrates, niacin, Lovaza, EPANOVA, Omtryg, and 10:42</p> <p>13 VASCEPA, correct? 10:42</p> <p>14 A Yes. 10:42</p> <p>15 Q Of those products, the only product that 10:42</p> <p>16 has been shown to reduce triglycerides in patients 10:42</p> <p>17 with very high triglycerides without raising LDL-C 10:42</p> <p>18 is VASCEPA, correct? 10:42</p> <p>19 MR. REIG-PLESSIS: Objection to form. 10:42</p> <p>20 A Okay. And I -- I would -- I would add -- 10:42</p> <p>21 again, we're talking about median changes typically 10:42</p> <p>22 in these clinical studies. 10:43</p> <p>23 But oftentimes there are many patients who 10:43</p> <p>24 do not get these benefits. And you can actually see 10:43</p> <p>25 an increase in LDL-C cholesterol, for example, in 10:43</p>
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<p>1 patients, even though the overall means go down or 10:43</p> <p>2 medians. So I think you have to interpret in 10:43</p> <p>3 this -- in that context. 10:43</p> <p>4 Q (BY MR. SIPES) But focus then on -- on 10:43</p> <p>5 medians. What happens to median patients? 10:43</p> <p>6 The only product approved for treatment of 10:43</p> <p>7 very high triglycerides that has been shown to 10:43</p> <p>8 reduce triglycerides without raising LDL-C is 10:43</p> <p>9 VASCEPA, correct? 10:43</p> <p>10 A Yes. 10:43</p> <p>11 MR. REIG-PLESSIS: Objection to form. 10:43</p> <p>12 Q (BY MR. SIPES) And the study that 10:43</p> <p>13 demonstrated that is the MARINE trial, correct? 10:43</p> <p>14 MR. REIG-PLESSIS: Same objection. 10:43</p> <p>15 A That's post the 2008 date that we're 10:43</p> <p>16 talking about here for the patents, are we -- is it 10:43</p> <p>17 not? 10:43</p> <p>18 Q (BY MR. SIPES) That -- do you know when 10:43</p> <p>19 MARINE published? 10:43</p> <p>20 A I think it was in 2004 or 2014. Sometime 10:43</p> <p>21 around there. 10:43</p> <p>22 Q It may be around 2010-2011 -- 10:43</p> <p>23 A Yeah. 10:43</p> <p>24 Q -- but -- 10:43</p> <p>25 A Yeah. Yeah. 10:43</p>	<p>1 Q -- it is after 2008? 10:44</p> <p>2 A Yes. 10:44</p> <p>3 Q The MARINE trial demonstrated that VASCEPA 10:44</p> <p>4 reduced triglycerides in very high triglyceride 10:44</p> <p>5 patients without raising LDL-C, correct? 10:44</p> <p>6 MR. REIG-PLESSIS: Objection to form. 10:44</p> <p>7 A It demonstrated that certain specific 10:44</p> <p>8 doses of VASCEPA, if I recall correctly, had that 10:44</p> <p>9 effect. 10:44</p> <p>10 Q (BY MR. SIPES) The dose was 4 grams per 10:44</p> <p>11 day, correct? 10:44</p> <p>12 A Yes. 10:44</p> <p>13 THE COURT REPORTER: 4 grams? 10:44</p> <p>14 MR. SIPES: 4 grams. Why don't we take a 10:44</p> <p>15 break. 10:44</p> <p>16 MR. REIG-PLESSIS: Yeah, I was about to 10:44</p> <p>17 say -- 10:44</p> <p>18 THE VIDEOGRAPHER: This marks the end of 10:44</p> <p>19 media file labeled numbered 2. Off the record at 10:44</p> <p>20 10:45 a.m. 10:44</p> <p>21 (A break was taken from 10:45 a.m. to 10:44</p> <p>22 10:59 a.m.) 10:44</p> <p>23 THE VIDEOGRAPHER: This marks the 10:52</p> <p>24 beginning of media file labeled No. 3. Back on the 10:57</p> <p>25 record at 10:59 a.m. 10:58</p>

<p style="text-align: right;">Page 146</p> <p>1 Q (BY MR. SIPES) Let me ask you to turn to 10:58 2 your rebuttal report -- report. That would be 10:58 3 Exhibit 2. 10:58 4 Paragraph 35, you -- you quote Amarin as 10:58 5 saying that JELIS supports VASCEPA being clinically 10:58 6 distinct from fibrates or niacin and being uniquely 10:58 7 positioned to plausibly provide CV benefit to 10:58 8 patients at high CV risk due to their atherogenic 10:58 9 lipid profile, specifically elevated TG despite 10:58 10 therapy -- statin therapy. 10:58 11 Do you see that? 10:58 12 A Yes. 10:58 13 MR. SIPES: And -- and just for the sake 10:58 14 of the court reporter, JELIS is all caps, J E L I S. 10:58 15 Q (BY MR. SIPES) Do you agree with this 10:58 16 statement that you quote from Amarin? 10:59 17 A I believe that JELIS was the first study 10:59 18 to provide convincing evidence that EPA, as 10:59 19 monotherapy on top of a statin, would lower 10:59 20 cardiovascular risk. 10:59 21 Q And do you think that the showing in JELIS 10:59 22 supports VASCEPA being clinically distinct from 10:59 23 fibrates or niacin on its basis of being able to 10:59 24 reduce cardiovascular risk on top of a statin? 10:59 25 A I believe that JELIS provided the 10:59</p>	<p style="text-align: right;">Page 147</p> <p>1 groundbreaking evidence and that VASCEPA builds on 10:59 2 that evidence. 10:59 3 Q And fibrates and niacin have not been 10:59 4 shown to reduce cardiovascular risk on top of a 10:59 5 statin, correct? 10:59 6 A That's correct. 11:00 7 Q So VASCEPA is the only agent approved for 11:00 8 treatment of very high triglycerides that has also 11:00 9 been shown to provide cardiovascular benefit to 11:00 10 patients on statin, correct? 11:00 11 A It's correct to state that it's the only 11:00 12 agent approved by the FDA based on very stringent 11:00 13 clinical -- clinical data, yes. 11:00 14 Q Okay. And if you turn to -- to 11:00 15 paragraph 65 of your rebuttal report -- you quote 11:00 16 Dr. Toth as saying, The fact that VASCEPA avoids 11:01 17 substantial LDL-C -- LDL-C increases in persons with 11:01 18 very high triglycerides gives the doctor the 11:01 19 flexibility to treat such patients in stepwise 11:01 20 fashion to start first with VASCEPA as monotherapy 11:01 21 to address pancreatitis risk; and then once TGs are 11:01 22 lowered below 500 milligrams per deciliter, to add a 11:01 23 statin, in combination with VASCEPA, to lower 11:01 24 cardiovascular risk. 11:01 25 Do you see that? 11:01</p>
<p style="text-align: right;">Page 148</p> <p>1 A Yes. 11:01 2 Q Do you agree with Dr. Toth that VASCEPA 11:01 3 avoids substantial LDL-C increases in persons with 11:01 4 very high triglycerides and gives doctors the 11:01 5 flexibility to treat such patients in stepwise 11:01 6 fashion? 11:01 7 A It provides one option for doctors to do 11:02 8 that. Although, there can be other options 11:02 9 available as well, such as combining omega-3 fatty 11:02 10 acids with a statin therapy, for example. 11:02 11 Q The -- the difference would be with 11:02 12 Lovaza, the statin would be added initially in order 11:02 13 to counteract the rising LDL-C seen with Lovaza, 11:02 14 correct? 11:02 15 A Well, I think -- I think the situation is 11:02 16 a little bit more complicated than that. First of 11:02 17 all, there's no evidence that -- I prefer to call it 11:02 18 EPA, since JELIS also showed the same thing. 11:02 19 There's no evidence that the benefits of 11:02 20 EPA in reducing cardiovascular risk in these 11:02 21 patients relates to changes in LDL cholesterol or 11:02 22 triglycerides. 11:02 23 And so I think that the idea that it's 11:02 24 working because it's avoiding the increase in LDL-C 11:02 25 is not substantiated by the clinical data here. 11:02</p>	<p style="text-align: right;">Page 149</p> <p>1 Q With respect to -- VASCEPA can be 11:02 2 administered to very high triglyceride patients 11:02 3 without raising LDL-C, correct? 11:02 4 A Yes. 11:03 5 Q And Lovaza will typically increase LDL-C 11:03 6 in patients with very high triglycerides, correct? 11:03 7 MR. REIG-PLESSIS: Objection to form. 11:03 8 A Can you restate that question, please? 11:03 9 Q (BY MR. SIPES) The -- the prescribing 11:03 10 information for Lovaza reports that LDL-C goes up 11:03 11 when administered to patients with very high 11:03 12 triglycerides, correct? 11:03 13 MR. REIG-PLESSIS: Objection to form. 11:03 14 A Actually, it shows that in some patients, 11:03 15 it goes up with omega-3 fatty acids, so in no way do 11:03 16 all patients treated with omega-3 fatty acids have 11:03 17 an increase in LDL cholesterol. 11:03 18 Q (BY MR. SIPES) Is Lovaza, when 11:03 19 administered to very high triglyceride patients, 11:03 20 typically prescribed in combination with a statin to 11:03 21 guard against a rise in LDL-C? 11:03 22 A Say -- I'm sorry. Say it again. 11:03 23 Q Is Lovaza, when administered to very high 11:03 24 triglyceride patients, typically coadministered with 11:03 25 a statin in order to guard against a rise in LDL-C? 11:03</p>

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<p>1 Q (BY MR. SIPES) Can -- 02:04</p> <p>2 A Do you -- 02:04</p> <p>3 Q How would a person of ordinary skill in 02:04</p> <p>4 the art determine the effect of EPA alone on LDL 02:04</p> <p>5 cholesterol, given the results in Kurabayashi? 02:04</p> <p>6 A Well, what you can conclude in this study 02:04</p> <p>7 is that in a patient treated with estriol, that EPA 02:04</p> <p>8 intervention lowers the LDL cholesterol relative to 02:04</p> <p>9 a person who is taking estriol that didn't get the 02:04</p> <p>10 EPA. 02:04</p> <p>11 So in other words, this is -- for this 02:04</p> <p>12 specific population where both groups were treated 02:04</p> <p>13 with estriol, EPA lowers the LDL cholesterol in 02:04</p> <p>14 that -- in that particular -- 02:04</p> <p>15 Q And -- 02:04</p> <p>16 A -- group. 02:04</p> <p>17 Q -- and that's what I'm trying 02:04</p> <p>18 to understand -- so -- and I don't understand -- is 02:04</p> <p>19 it your testimony that the data in Kurabayashi 02:04</p> <p>20 suggests that the group that received EPA on top of 02:04</p> <p>21 estriol, saw greater reductions in LDL-C than the 02:04</p> <p>22 patients who only received estriol? 02:05</p> <p>23 MR. REIG-PLESSIS: Objection to form; 02:05</p> <p>24 mischaracterizes. 02:05</p> <p>25 A Yeah, I'm sorry. You're going to have to 02:05</p>	<p>1 say that again. 02:05</p> <p>2 Q (BY MR. SIPES) Is it your testimony that 02:05</p> <p>3 from Kurabayashi, the patients who received EPA on 02:05</p> <p>4 top of estriol, saw greater reductions in LDL-C than 02:05</p> <p>5 the control group that received estriol alone? 02:05</p> <p>6 MR. REIG-PLESSIS: Same objection. 02:05</p> <p>7 A I think what we can conclude is that both 02:05</p> <p>8 groups saw a significant decrease in LDL 02:05</p> <p>9 cholesterol. 02:05</p> <p>10 Q (BY MR. SIPES) And would the conclusion be 02:05</p> <p>11 from that that the estriol was decreasing the LDL 02:05</p> <p>12 cholesterol? 02:05</p> <p>13 A Not necessarily. And I have noticed in 02:05</p> <p>14 reviewing the papers for this that a lot of the 02:05</p> <p>15 studies, the LDL cholesterol levels tend to go down 02:05</p> <p>16 over time. 02:05</p> <p>17 That was observed in JELIS as well. And I 02:05</p> <p>18 have noticed that in many of the other studies. So 02:05</p> <p>19 there's -- there are other factors that can be 02:05</p> <p>20 affecting LDL cholesterol in this study. 02:06</p> <p>21 Q But -- but it's fair to say from the 02:06</p> <p>22 results presented in Kurabayashi that EPA did not, 02:06</p> <p>23 in a statistically significant way, reduce LDL-C 02:06</p> <p>24 cholesterol compared to control? 02:06</p> <p>25 A Okay. I'm having to look at the figure 02:06</p>
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<p>1 legend here, because I think this is a fairly 02:06</p> <p>2 technical point. 02:06</p> <p>3 Yes, okay, I think that's reasonable 02:06</p> <p>4 conclusion. It looks like there were similar 02:06</p> <p>5 reductions in LDL cholesterol in both groups. 02:06</p> <p>6 Q Right. Numerically, estriol alone reduced 02:06</p> <p>7 LDL-C to a greater extent than estriol plus EPA, 02:06</p> <p>8 correct? 02:07</p> <p>9 A Well -- 02:07</p> <p>10 MR. REIG-PLESSIS: Objection to form. 02:07</p> <p>11 A -- I think the correct interpretation is 02:07</p> <p>12 there's no statistical difference between the two 02:07</p> <p>13 groups. 02:07</p> <p>14 Q (BY MR. SIPES) Right. The -- which is to 02:07</p> <p>15 say the addition of EPA to estriol did not make any 02:07</p> <p>16 statistically significant difference on LDL-C? 02:07</p> <p>17 A I think it would be correct to say that in 02:07</p> <p>18 this particular study in these patients, yes. 02:07</p> <p>19 Q And the baseline triglycerides in the 02:07</p> <p>20 Kurabayashi study -- 02:07</p> <p>21 A I just want to -- some of these studies 02:07</p> <p>22 were in a subset, I believe. Is that correct or is 02:07</p> <p>23 that -- let me just look -- may I look at the 02:07</p> <p>24 text -- 02:07</p> <p>25 Q Sure. 02:07</p>	<p>1 A -- for a minute? Okay. 02:07</p> <p>2 This is the overall population, I believe, 02:08</p> <p>3 in this particular study. 02:08</p> <p>4 Q The -- the baseline triglycerides in 02:08</p> <p>5 Kurabayashi was 135.6 milligrams per deciliter for 02:08</p> <p>6 the EPA group, correct? 02:08</p> <p>7 A Yes. 02:08</p> <p>8 Q So those are normal triglyceride levels? 02:08</p> <p>9 A They're less than 150 milligrams per 02:08</p> <p>10 deciliter. 02:08</p> <p>11 Q So Kurabayashi was not conducted in a 02:08</p> <p>12 hypertriglyceridemic patient population? 02:08</p> <p>13 A No. 02:08</p> <p>14 Q If you'll turn to page 523, the right-hand 02:08</p> <p>15 column -- 02:09</p> <p>16 A Yes. 02:09</p> <p>17 Q -- there's a sentence that says, The 02:09</p> <p>18 proportion of cases showing improvement of 02:09</p> <p>19 triglyceride levels was 10 percent, 2 of 20, and 02:09</p> <p>20 55 percent of 11 of 20 respectively. 02:09</p> <p>21 Do you see that? 02:09</p> <p>22 A Boy, they -- they keep saying the same -- 02:09</p> <p>23 it's -- it's going to take me a minute because they 02:09</p> <p>24 keep repeating the same phraseology all the way 02:09</p> <p>25 through here. Can you repeat that one more time -- 02:09</p>

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<p>1 Q Yes. 02:09</p> <p>2 A -- for me? 02:09</p> <p>3 Q There's a reference to, The proportion of 02:09</p> <p>4 cases showing improvement of triglyceride levels was 02:09</p> <p>5 10 percent, 2 of 20, and 55 percent, 11 of, 20 02:09</p> <p>6 respectively. 02:09</p> <p>7 A Okay. Let me just review this. Yes. 02:09</p> <p>8 Q So at least for those patients that 02:10</p> <p>9 continued to the end of the study, 45 percent of 02:10</p> <p>10 them that were on EPA plus estriol did not see 02:10</p> <p>11 improvements in triglyceride levels, correct? 02:10</p> <p>12 A According to the criteria, they don't 02:10</p> <p>13 really define here what they mean by "improvement in 02:10</p> <p>14 triglyceride levels," and so I think that makes that 02:10</p> <p>15 statement somewhat ambiguous. 02:10</p> <p>16 Q So would a person of ordinary skill in the 02:10</p> <p>17 art in 2008 be able to understand that statement? 02:10</p> <p>18 A I think they would say there's -- appears 02:10</p> <p>19 to be a difference between the two groups, but we 02:10</p> <p>20 don't know exactly what that means because they 02:10</p> <p>21 don't define what they're talking about. 02:10</p> <p>22 Q For purposes of developing a treatment for 02:10</p> <p>23 very high triglycerides, what response rate would be 02:10</p> <p>24 desirable in the TG-lowering agent -- 02:10</p> <p>25 MR. REIG-PLESSIS: Objection to form. 02:10</p>	<p>1 Q (BY MR. SIPES) -- or what -- what response 02:10</p> <p>2 would be considered acceptable? 02:10</p> <p>3 MR. REIG-PLESSIS: Same objection. 02:10</p> <p>4 A I think, again, it's a very broad 02:11</p> <p>5 question. And I think that you would have to define 02:11</p> <p>6 more carefully what the clinical population was. 02:11</p> <p>7 You would have to give me additional 02:11</p> <p>8 information about what exact circumstances you're 02:11</p> <p>9 talking about. Are these diabetics? Nondiabetics? 02:11</p> <p>10 People with heart disease? People without heart 02:11</p> <p>11 disease? 02:11</p> <p>12 I think there's a lot of variables in that 02:11</p> <p>13 equation. 02:11</p> <p>14 MR. SIPES: I think this would be a good 02:11</p> <p>15 time for, among other things, a break. 02:11</p> <p>16 THE VIDEOGRAPHER: This marks the end of 02:11</p> <p>17 media file labeled No. 5. Off the record at 02:11</p> <p>18 2:12 p.m. 02:11</p> <p>19 (A break was taken from 2:12 p.m. to 02:11</p> <p>20 2:27 p.m.) 02:11</p> <p>21 THE VIDEOGRAPHER: This marks the 02:25</p> <p>22 beginning of media file labeled No. 6. Back on the 02:25</p> <p>23 record 2:27 p.m. 02:25</p> <p>24 Q (BY MR. SIPES) I'm going to hand you 02:26</p> <p>25 Exhibit 16. 02:26</p>
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<p>1 (Exhibit 16 was marked for identification 02:26</p> <p>2 and is attached to the transcript.) 02:26</p> <p>3 Q (BY MR. SIPES) Do you recognize Exhibit 16 02:26</p> <p>4 as U.S. Patent 8,293,728 that is at issue in this 02:26</p> <p>5 case? 02:26</p> <p>6 A Yes. 02:26</p> <p>7 Q And are you familiar with the practice of 02:26</p> <p>8 referring to a patent by its last three numbers? 02:26</p> <p>9 A I am. 02:26</p> <p>10 Q So would it be all right if we refer to 02:26</p> <p>11 Exhibit 16 at the '728 Patent? 02:26</p> <p>12 A Yes. 02:26</p> <p>13 Q Now, I want you to look at your reply 02:26</p> <p>14 report, Exhibit 3, paragraph 25. 02:26</p> <p>15 A So where am I looking now? 02:26</p> <p>16 Q Your reply report, paragraph 25. It's on 02:26</p> <p>17 page 7. 02:27</p> <p>18 A I'm trying to move the paper away from 02:27</p> <p>19 myself. Okay. Yes. 02:27</p> <p>20 Q In the first sentence of paragraph 25, you 02:27</p> <p>21 state, To be clear, under my definition, a POSA 02:27</p> <p>22 would have had a high level of skill relevant to the 02:27</p> <p>23 asserted patents. 02:27</p> <p>24 Do you see that? 02:27</p> <p>25 A Yes. 02:27</p>	<p>1 Q Why, in your opinion, would a person of 02:27</p> <p>2 ordinary skill in the art, for purposes of the 02:27</p> <p>3 asserted patents in this case, have had a high level 02:27</p> <p>4 of skill? 02:27</p> <p>5 A Well, I think evaluating whether or not 02:27</p> <p>6 something is actually significantly different -- in 02:27</p> <p>7 other words, if something really is a new invention 02:27</p> <p>8 versus what was present in the art before requires a 02:27</p> <p>9 fairly sophisticated knowledge of biochemistry and 02:27</p> <p>10 physiology. 02:27</p> <p>11 Q Do you think it would require a 02:27</p> <p>12 sophisticated knowledge of biochemistry and 02:27</p> <p>13 physiology -- 02:27</p> <p>14 A Not -- 02:27</p> <p>15 Q -- okay. Let's -- 02:28</p> <p>16 A -- I'm stopping. I'm stopping. 02:28</p> <p>17 Q Did you develop your -- your definition of 02:28</p> <p>18 a person of ordinary skill in the art based on what 02:28</p> <p>19 would be required to evaluate the patentability of 02:28</p> <p>20 the invention claimed in the asserted patents? 02:28</p> <p>21 MR. REIG-PLESSIS: Objection to form. 02:28</p> <p>22 A I think it would be required to evaluate 02:28</p> <p>23 the totality of the evidence that's supporting 02:28</p> <p>24 the -- the claims of the patent, would be my 02:28</p> <p>25 evaluation. 02:28</p>

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<p>1 Q (BY MR. SIPES) All right. And what sort 02:28</p> <p>2 of knowledge would be required to evaluate the 02:28</p> <p>3 evidence supporting the claims of the patents? 02:28</p> <p>4 A Well, I think we outline it here. I would 02:28</p> <p>5 probably pretty much stick with what the definition 02:28</p> <p>6 here is, as -- 02:28</p> <p>7 Q And -- 02:28</p> <p>8 A -- as outlined in paragraph 25. 02:28</p> <p>9 Q Okay. So that would require a knowledge 02:28</p> <p>10 of -- of lipid biochemistry, correct? 02:29</p> <p>11 MR. REIG-PLESSIS: Objection to form; 02:29</p> <p>12 mischaracterizes. 02:29</p> <p>13 A Yeah, I -- I think the way this is meant 02:29</p> <p>14 to explain it is -- is there could be different 02:29</p> <p>15 areas within this context -- in this definition. 02:29</p> <p>16 You wouldn't necessarily have to have every single 02:29</p> <p>17 one of these things. 02:29</p> <p>18 Q (BY MR. SIPES) Do you believe that you 02:29</p> <p>19 would need a medical degree? 02:29</p> <p>20 A I do not. 02:29</p> <p>21 Q Okay. If -- if a person didn't have a 02:29</p> <p>22 medical degree, what would they need to evaluate the 02:29</p> <p>23 evidence in the patent? 02:29</p> <p>24 A I think they would have to have extensive 02:29</p> <p>25 experience in the lipid field, practical experience. 02:29</p>	<p>1 They would have to have a detailed familiarity with 02:29</p> <p>2 the literature, and they would have to have some 02:29</p> <p>3 basic knowledge of pharmacology and biochemistry. 02:29</p> <p>4 Q And when you say to have "practical 02:29</p> <p>5 experience in the field," what -- if somebody wasn't 02:29</p> <p>6 a medical doctor, that experience would not involve 02:29</p> <p>7 treating patients, correct? 02:30</p> <p>8 A Well, that would not involve prescribing 02:30</p> <p>9 treatment for patients. 02:30</p> <p>10 Q Okay. 02:30</p> <p>11 A So for example, let's just imagine a Ph.D. 02:30</p> <p>12 They might not be able to write a prescription for 02:30</p> <p>13 treating a patient, but I know Ph.D.s in the field 02:30</p> <p>14 who are extremely knowledgeable about many, many 02:30</p> <p>15 different aspects of -- of this area and would be 02:30</p> <p>16 capable of making a very well-informed judgment. 02:30</p> <p>17 Q And would a person with a Ph.D. evaluating 02:30</p> <p>18 the evidence supporting the invention, consult with 02:30</p> <p>19 a physician or other medical doctor? 02:30</p> <p>20 A Not necessarily. I think, again, it 02:30</p> <p>21 depends on your experience. 02:30</p> <p>22 And as I'm learning in this -- this 02:30</p> <p>23 session right here with you guys, as well as my 02:30</p> <p>24 interactions with my team, lawyers can have a very 02:30</p> <p>25 good knowledge of what's going on in this area 02:30</p>
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<p>1 because they're extremely familiar with the 02:30</p> <p>2 literature and they know a lot of the wrinkles 02:31</p> <p>3 relevant to it. 02:31</p> <p>4 So I think it's really a matter of what 02:31</p> <p>5 exactly their knowledge is. 02:31</p> <p>6 Q Okay. But -- but you're not suggesting a 02:31</p> <p>7 person of ordinary skill in the art would need 02:31</p> <p>8 excess to a lawyer, I take it? 02:31</p> <p>9 A No. No. 02:31</p> <p>10 Q Yeah. Okay. You don't include within the 02:31</p> <p>11 skill set of the -- of the team to which a person of 02:31</p> <p>12 skill would have access, a biostatistician, I take 02:31</p> <p>13 it? 02:31</p> <p>14 MR. REIG-PLESSIS: Objection to form. 02:31</p> <p>15 A I think that would depend on the 02:31</p> <p>16 particular circumstances. And I -- really trying to 02:31</p> <p>17 specify every single thing that you need to 02:31</p> <p>18 understand these things depends on the precise 02:31</p> <p>19 circumstances of what's being evaluated and what's 02:31</p> <p>20 involved. 02:31</p> <p>21 So in some circumstances you -- you might 02:31</p> <p>22 need to have a very detailed evaluation of 02:31</p> <p>23 biostatistics. And for example, in my area -- one 02:31</p> <p>24 my areas of research, we do very large numbers of 02:31</p> <p>25 protein measurements in lipoproteins. 02:32</p>	<p>1 And since we're measuring so many 02:32</p> <p>2 different things in so many different people, trying 02:32</p> <p>3 to interpret that data would require someone with 02:32</p> <p>4 biostatistical expertise. And for example, we get 02:32</p> <p>5 that kind of expertise when we need it. 02:32</p> <p>6 On the other hand, if you're trying to 02:32</p> <p>7 interpret many clinical studies, I think that you 02:32</p> <p>8 don't necessarily need a strong biostatistical 02:32</p> <p>9 background. And even just taking it at more or less 02:32</p> <p>10 face value, the p-values. And assuming that they 02:32</p> <p>11 have a reasonable understanding of -- of statistics, 02:32</p> <p>12 what a p-value test is, what a -- what some of the 02:32</p> <p>13 standard tests are, that might be adequate. So it 02:32</p> <p>14 very much depends on the exact -- on the exact 02:32</p> <p>15 nature of what it is you are trying to -- to do. 02:32</p> <p>16 Q Okay. 02:32</p> <p>17 A I think it's a -- it's a complicated area. 02:32</p> <p>18 Q The patent describes a -- a clinical study 02:32</p> <p>19 of 4 grams of EPA, correct, in Column 13 -- 02:32</p> <p>20 MR. REIG-PLESSIS: Objection to form. 02:32</p> <p>21 Q (BY MR. SIPES) -- the -- the patent -- the 02:32</p> <p>22 '728 Patent? 02:32</p> <p>23 A I'm sorry? Where is that? 02:32</p> <p>24 Q It's Exhibit -- 02:32</p> <p>25 A Oh -- 02:33</p>

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1	Q -- 16.	02:33	1	Q -- pure ester?	02:33
2	A -- right in front of me. And correct me	02:33	2	A -- yeah, pure. 9 -- greater than	02:34
3	if I'm wrong here, but that would be under the	02:33	3	96 percent pure EPA and ester of that form of the --	02:34
4	claims?	02:33	4	the --	02:34
5	Q No. No. No. Column 13, the example.	02:33	5	Q And that --	02:34
6	A Okay. Please restate the question.	02:33	6	A -- fatty acid.	02:34
7	Q The -- the example describes a	02:33	7	Q -- and the -- and what the patent is	02:34
8	placebo-controlled, randomized, double-blind 12-week	02:33	8	describing in the example is the administration of	02:34
9	study with open-label extension conducted on EPA,	02:33	9	pure EPA to patients with fasting triglyceride	02:34
10	correct?	02:33	10	levels of 500 and above, correct --	02:34
11	MR. REIG-PLESSIS: Objection to form;	02:33	11	MR. REIG-PLESSIS: Objection to form.	02:34
12	mischaracterizes.	02:33	12	Q (BY MR. SIPES) -- 500 milligrams per	02:34
13	A I -- I think I would have to go with what	02:33	13	deciliter above, correct?	02:34
14	the text says. It says a placebo -- a multicenter	02:33	14	MR. REIG-PLESSIS: Same objection.	02:34
15	placebo -- it says what it says. I would go with	02:33	15	A Well, I can quote what it says, With	02:34
16	the --	02:33	16	fasting triglyceride levels of greater than or equal	02:34
17	Q (BY MR. SIPES) Right.	02:33	17	to 500 milligrams per deciliter and less than or	02:34
18	A -- text there.	02:33	18	equal to 1,500 milligrams per deciliter with	02:34
19	Q And "AMR101," do you understand the	02:33	19	definitions provided as well in millimoles per	02:34
20	reference to "AMR101 in '728 Patent?"	02:33	20	liter.	02:34
21	A I do.	02:33	21	Q (BY MR. SIPES) So would a person of	02:34
22	Q And what is AMR101?	02:33	22	ordinary skill in the art in light of the study	02:34
23	A EPA --	02:33	23	described there, do you believe that would require	02:34
24	Q That -- that's --	02:33	24	consultation with a biostatistician to interpret the	02:34
25	A -- ester --	02:33	25	results of that study?	02:34
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1	MR. REIG-PLESSIS: Objection to form and	02:34	1	statistical significance does not necessarily mean	02:36
2	as to "results."	02:34	2	it's clinically significant. Right.	02:36
3	A I mean, there's a lot of things that are	02:35	3	So I think, again, that requires judgment	02:36
4	missing from this particular statement. So again,	02:35	4	about what the overall context in the field is and	02:36
5	you're making some very broad statements.	02:35	5	what a significant improvement would be.	02:36
6	You don't specify what the number of	02:35	6	Q And would -- judgments about the clinical	02:36
7	subjects studied is going to be. You don't discuss	02:35	7	significance of the results, that would require a	02:36
8	what your power calculations are. You don't specify	02:35	8	medical degree?	02:36
9	what you're going to consider significant and	02:35	9	A Not necessarily. I think -- I know	02:36
10	nonsignificant. So this is -- I mean, this is sort	02:35	10	Ph.D.s. I have worked with Ph.D.s that I felt were	02:36
11	of a very bare-bones description of what -- what you	02:35	11	qualified to make that kind of a judgment.	02:36
12	would really need to do to evaluate that.	02:35	12	Q And --	02:36
13	Q So when you were defining your person of	02:35	13	A And I will mention in passing: I know	02:36
14	ordinary skill in the art, were you taking into	02:35	14	M.D.s that are not qualified to make that kind of a	02:36
15	account the skill that would be necessary to	02:35	15	judgment, so I don't think it's really whether you	02:36
16	evaluate the results?	02:35	16	have a Ph.D. or an M.D. Yeah.	02:36
17	A Yes.	02:35	17	Q Did you, in -- in determining what the	02:36
18	Q Okay. And in your view, that would	02:35	18	skill level is "of a person of ordinary skill,"	02:36
19	require a high level of skill?	02:35	19	evaluate the level of skill of the inventors named	02:36
20	A No. In my view, it would require more	02:35	20	on the patent?	02:36
21	information and an adequate technical background.	02:35	21	A I did not.	02:36
22	It -- and again, you're making very broad	02:35	22	Q Okay. Do you know the skill level of the	02:37
23	statements here, and I think the issue very much	02:35	23	inventors named on the patent?	02:37
24	depends on the particulars.	02:35	24	A I do not.	02:37
25	And I'll also add that just achieving	02:35	25	Q Okay. At this time in March of 2008, do	02:37

<p style="text-align: right;">Page 354</p> <p>1 at 4:12 p.m. 04:11</p> <p>2 04:11</p> <p>3 (TIME NOTED: 4:12 p.m.)</p> <p>4</p> <p>5</p> <p>6</p> <p>7</p> <p>8</p> <p>9</p> <p>10</p> <p>11</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>	<p style="text-align: right;">Page 355</p> <p>1</p> <p>2</p> <p>3</p> <p>4 I, JAY W. HEINECKE, M.D., do hereby declare</p> <p>5 under penalty of perjury that I have read the</p> <p>6 foregoing transcript; that I have made any</p> <p>7 corrections as appear noted, in ink, initialed by</p> <p>8 me, or attached hereto; that my testimony as</p> <p>9 contained herein, as corrected, is true and correct.</p> <p>10 EXECUTED this _____ day of _____,</p> <p>11 20____, at _____, _____.</p> <p style="text-align: center;">(City) (State)</p> <p>12</p> <p>13</p> <p>14</p> <p>15 _____</p> <p>16 JAY W. HEINECKE, M.D.</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>
<p style="text-align: right;">Page 356</p> <p>1 I, MARY J. GOFF, CSR No. 13427, Certified</p> <p>2 Shorthand Reporter of the State of California,</p> <p>3 certify;</p> <p>4 That the foregoing proceedings were taken</p> <p>5 before me at the time and place herein set forth, at</p> <p>6 which time the witness declared under penalty of</p> <p>7 perjury; that the testimony of the witness and all</p> <p>8 objections made at the time of the examination were</p> <p>9 recorded stenographically by me and were thereafter</p> <p>10 transcribed under my direction and supervision; that</p> <p>11 the foregoing is a full, true, and correct</p> <p>12 transcript of my shorthand notes so taken and of the</p> <p>13 testimony so given;</p> <p>14 That before completion of the deposition,</p> <p>15 review of the transcript (XX) was () was not</p> <p>16 requested: () that the witness has failed or</p> <p>17 refused to approve the transcript.</p> <p>18 I further certify that I am not financially</p> <p>19 interested in the action, and I am not a relative or</p> <p>20 employee of any attorney of the parties, nor of any</p> <p>21 of the parties.</p> <p>22 I declare under penalty of perjury under the</p> <p>23 laws of California that the foregoing is true and</p> <p>24 correct, dated this 30th day of July, 2019.</p> <p>25 _____</p> <p style="text-align: center;">MARY GOFF</p>	<p style="text-align: right;">Page 357</p> <p>2 DATE OF DEPOSITION:</p> <p>3 NAME OF WITNESS:</p> <p>4 Reason Codes:</p> <p>5 1. To clarify the record.</p> <p>6 2. To conform to the facts.</p> <p>7 3. To correct transcription errors.</p> <p>8 Page _____ Line _____ Reason _____</p> <p>9 From _____ to _____</p> <p>10 Page _____ Line _____ Reason _____</p> <p>11 From _____ to _____</p> <p>12 Page _____ Line _____ Reason _____</p> <p>13 From _____ to _____</p> <p>14 Page _____ Line _____ Reason _____</p> <p>15 From _____ to _____</p> <p>16 Page _____ Line _____ Reason _____</p> <p>17 From _____ to _____</p> <p>18 Page _____ Line _____ Reason _____</p> <p>19 From _____ to _____</p> <p>20 Page _____ Line _____ Reason _____</p> <p>21 From _____ to _____</p> <p>22 Page _____ Line _____ Reason _____</p> <p>23 From _____ to _____</p> <p>24</p> <p>25 _____</p>